

April 30, 1999

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Center: Patient Initials: Rand Number: Form completed by: **A. VISIT INFORMATION**

1. Visit: ☐ 06 6 month ☐ 12 12 month ☐ 18 18 month ☐ 24 24 month
G_VISIT ☐ 30 30 month ☐ 36 36 month ☐ 42 42 month ☐ 99 Non-routine
2. Date of visit: **Recoded as G_VISDY = days from randomization** / /
Month Day Year
3. Type of contact: **G_VISTP** ☐ 1 Visit ☐ 3 Phone ☐ 5 Mail

B. ADHERENCE (complete at every visit while participant is on study medication)

1. Number of HRT/HRT placebo pills left: **G_HRTCNT**
2. Number of Vitamin C/Vitamin C placebo pills left: **G_CCNT**
3. Number of Vitamin E/Vitamin E placebo pills left: **G_ECNT**

C. STUDY DRUG DISPENSATION (complete for every contact)

1. Bottle code of HRT study medication dispensed: **deleted**
2. Bottle code of Vitamin C study medication dispensed: **deleted**
3. Bottle code of Vitamin E study medication dispensed: **deleted**
4. Open label multivitamin dispensed? **G_MULTI** Y₁ N₃

D. PHYSICAL MEASURES (required at 12, 24 and 36 months)

1. Blood pressure (mmHg): **G_SBP / G_DBP** /
Systolic Diastolic
2. Height: **G_HTCM** cm OR ft in
3. Weight: **G_WTKG** kg OR lb oz
4. Waist circumference: **G_WCCM** cm OR in
5. Hip circumference: **G_HCCM** cm OR in

E. PROCEDURES CHECKLIST

1. Fasting study bloods drawn? (required at 18 and 36 months) **G_FBL** Y₁ N₃
- a. If Yes, date of samples: **Recoded as G_FBLDY = days since randomization** / /
Month Day Year
2. ECG done? (required at 12 and 36 months) **G_ECG** Y₁ N₃
- If Yes, answer questions a. and b. below. If No, continue to section F.
- a. Date of ECG: **Recoded as G_ECGDY = days since randomization** / /
Month Day Year
- b. Was atrial fibrillation found on the ECG? **G_ECGAF** Y₁ N₃
- 1) If atrial fibrillation, have oral anticoagulants been prescribed? **G_ANTICO** Y₁ N₃

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Center: _____

Patient Initials: _____, _____

Rand Number: _____

Form
completed by: _____**F. INTERIM MEDICAL HISTORY** (*complete for every contact*)**1. Since the last semi-annual visit, have you had:**

- a. Coronary angiogram, angioplasty (including stent) or bypass surgery?
- G_CORINT**

Y₁ N₃*If Yes, send all angiograms to the Central Angiography Laboratory*

- b. Carotid or peripheral vascular angiogram, angioplasty (including stent) or surgery?
- G_CARANG**

Y₁ N₃

- c. Overnight hospitalization for any reason?
- G_HOSP**

Y₁ N₃

- d. Bleeding (other than associated with surgery or angioplasty) that required blood transfusion?
- G_BLEED**

Y₁ N₃

- e. A fracture?
- G_FX**

Y₁ N₃*If necessary, obtain records and complete the Outcomes Form W09.***2. In the past 4 weeks, have you had any chest discomfort? **G_PAIN4****Y₁ N₃*If YES, answer a. through e. If NO chest discomfort, go to section G.*

- a. does this usually occur with exercise, such as walking, climbing stairs, carrying something, or sexual activity?
- G_STAIRS**

Y₁ N₃

- b. does this usually occur with emotion, such as excitement, stress, tension, or anger?

Y₁ N₃**G_EMOTE**

- c. does this awaken you from sleep?
- G_AWAKEN**

Y₁ N₃

- d. did you have any chest discomfort at rest?
- G_CDREST**

Y₁ N₃

- e. Choose only one of the following descriptions of the typical level of your discomfort over the past 4 weeks.
- G_LEVEL**

- ☐ 1 Ordinary physical activity does not cause angina, or angina only with strenuous or rapid or prolonged exertion.
- ☐ 3 Slight limitation of ordinary activity. Walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, or in cold may cause angina.
- ☐ 5 Marked limitation of ordinary physical activity. Walking one to two blocks on the level and climbing one flight of stairs under normal conditions and at normal pace may cause angina.
- ☐ 7 Inability to carry on physical activity without angina or chest pain.

| | | | |
|------------------------------|---|---|-------------|
| WAVE TRIAL | FOLLOW UP FORM | | FORM W07 |
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G. CURRENT MEDICATIONS

Please answer all the questions below. If the answer to some questions is unknown, write an asterisk (*) in the shaded area.

1. Lipid Lowering Agents:

- | | |
|---|-------------------------------|
| a. HMG co-A reductase inhibitor G_HMG | Y ₁ N ₃ |
| b. Fibrin acid derivative? G_FIBRIC | Y ₁ N ₃ |
| c. Niacin (nicotinic acid)? G_NIACIN | Y ₁ N ₃ |
| d. Resins? G_RESINS | Y ₁ N ₃ |
| e. Others? G_OTHLLA | Y ₁ N ₃ |

2. Diabetes drugs:

- | | |
|---------------------------------|-------------------------------|
| a. Insulin? G_INSUL | Y ₁ N ₃ |
| b. Oral agents? G_POHGLY | Y ₁ N ₃ |

3. Calcium channel blockers:

- | | |
|---|-------------------------------|
| a. Dihydropyridine? G_DIHY | Y ₁ N ₃ |
| b. Other calcium channel blockers? G_OTHCCB | Y ₁ N ₃ |

4. Open label medications:

- | | |
|--|-------------------------------|
| a. Estrogen? G_OLHRT | Y ₁ N ₃ |
| b. Vitamin C (other than multivitamins)? G_OLVITC | Y ₁ N ₃ |
| c. Vitamin E (other than multivitamins)? G_OLVITE | Y ₁ N ₃ |

5. Other Current Medications:

- | | |
|--|-------------------------------|
| a. Digoxin/Lanoxin? G_DIG | Y ₁ N ₃ |
| b. Beta blockers? G_BETA | Y ₁ N ₃ |
| c. Nitrates, oral or topical? (excluding sublingual NTG) G_NITR | Y ₁ N ₃ |
| d. Aspirin? G_ASPRIN | Y ₁ N ₃ |
| e. Other antiplatelet agents? G_ANTIPL | Y ₁ N ₃ |
| f. Warfarin (coumadin)? G_WARF | Y ₁ N ₃ |
| g. Heparin or low molecular weight heparin (Enoxaparin)? G_HEPRIN | Y ₁ N ₃ |
| h. ACE inhibitors? G_ACE | Y ₁ N ₃ |
| i. Diuretics? G_DIUR | Y ₁ N ₃ |
| j. Blood pressure lowering agents (other than calcium channel blockers, diuretics, beta blockers, or ACE inhibitors)? G_BPLOW | Y ₁ N ₃ |
| k. Antiarrhythmics? G_ANTIAR | Y ₁ N ₃ |